



Patent US 515  
Attorney Docket 612,406-026  
[formerly Docket 271/149]

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

**Thomas Wagner, et al.**

**Serial No.: 09/868,824**

Filed: September 18, 2001

For: **TEST SYSTEM FOR DETECTING  
DIFFERENT MARKERS, AND  
PRODUCTION AND USE THEREOF**

Group Art Unit: 1634

Examiner: J. Fredman

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In accordance with 37 CFR §§ 1.97 and 1.98, the items identified in this Information Disclosure Statement ("IDS") are brought to the attention of the Office. In accordance with §1.98(d), copies of some or all of the references listed on the attached Form PTO-1449 are not enclosed herewith because they were previously cited by or submitted to the Patent and Trademark Office in prior Application Serial Nos. 09/132,354 and 09/616,985, for which a claim for priority under 35 U.S.C. §120 has been made in the instant application. Accordingly, Applicants will provide duplicate copies in respect of the present case only if the Examiner so desires.

The items identified in this IDS may or may not be "material" pursuant to 37 CFR § 1.56. The submission thereof by Applicant is not to be construed as an admission that any such patent, publication or other information referred to therein is material or considered to be material (37 CFR § 1.97(h)), or even qualifies as "prior art" under 35 USC § 102 with respect to this invention unless specifically designated by Applicant as such.

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CERTIFICATE OF MAILING UNDER 37 CFR 1.8

I hereby certify that this document (along with any referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as First Class Mail in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Date: June 11, 2003  
IR1:1040552.1

Sent by: Cynthia B. Pacheco

Signature:

*Cynthia B. Pacheco*

**INFORMATION DISCLOSURE STATEMENT FILING PROVISION:**

☐ This IDS is believed to be timely in that it is being submitted under 37 CFR § 1.97(b), that is (1) within three months of the filing date of the application, which is not a continued prosecution application filed under § 1.53(d); or (2) within three months of entry of the national stage as set forth in 37 CFR § 1.491; or (3) before the mailing of a first Office action on the merits; or (4) before the mailing of a first Office action after filing a request for continued examination under § 1.114. Thus, no fee is required.

☐ However, if the undersigned is in error in this regard, Applicant respectfully requests that the Office consider this IDS as filed under 37 CFR § 1.97(c), if applicable, and charge the fee due under 37 CFR § 1.17(p) to the deposit account referenced below.

☐ However, if the undersigned is in error in this regard, Applicant respectfully requests that the Office consider this IDS as filed under 37 CFR § 1.97(c), if applicable, and a statement under 37 CFR § 1.97(e) is included below, thus no fee is required.

☒ This IDS is being submitted under 37 CFR § 1.97(c), that is after mailing of a first Office action on the merits, but before a Final Action under 37 CFR § 1.113 or a Notice of Allowance under 37 CFR § 1.311.

☒ The fee due under 37 CFR § 1.17(p) is submitted herewith.

☐ A statement under 37 CFR § 1.97(e) is included below, thus no fee is required. In the event that this IDS is not received before a Final Action or a Notice of Allowance, then Applicant respectfully requests that the Office consider the filing of these papers to be submitted under 37 CFR § 1.97(d) and charge the fee due under 37 CFR § 1.17(p) to the deposit account below.

☐ This IDS is being submitted under 37 CFR § 1.97(d), that is after a Final Action under 37 CFR § 1.113 or a Notice of Allowance under 37 CFR § 1.311, but before payment of the issue fee. A statement under 37 CFR § 1.97(e) is included below. The fee due under 37 CFR § 1.17(p) is submitted herewith.

**Statement Under 37 CFR § 1.97(e):**

☐ No item contained in this IDS was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this statement after making reasonable inquiry, no item of information contained in this IDS was known to any individual designated in 37 CFR § 1.56(c) more than three months prior to the filing of this IDS.

**PAYMENT AND/OR AUTHORIZATION TO CHARGE FEES:**

- ☒ A check (No. 576795) in the amount of \$180.00 is enclosed for the above fee(s).  
☐ Please charge \_\_\_\_\_ to Deposit Account No. 50-0639 for the above fee(s).

The Commissioner is authorized to charge any fees required by the filing of these papers, and to credit any overpayment to O'Melveny and Myer's Deposit Account No. 50-0639.

Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.

References AD is in a language other than the English language. A concise explanation of relevance is given below.

**Ref AD:** German Patent Application DE 37 159 84 A1 has an equivalent UK patent Application GB 2190490 (Ref AE). It discusses an enzyme immunoassay for the measurement of antigen, with improved sensitivity. The immunoassay comprises the steps of (1) reacting [A] an immune-complex, obtained by reacting, at one time, (a) the antigenic substance, (b) an immobilized first antibody recognizing the antigenic substance and (c) a second antibody recognizing the antigenic substance originating from a different animal species, with [B] an enzyme-labeled third antibody recognizing immunoglobulin originating from the same animal species as said second antibody; (2) separating a solid phase from the liquid phase; and (3) measuring the amount of said enzyme present in the solid phase by means of the enzyme activity. The antigen may be carcinoembryonic antigen, thyroid stimulation hormone, human chorionic gonadotropin beta sub unit or hepatitis B virus.

Items AA and AF were first cited in a communication from a foreign patent office in a counterpart foreign application more than three months prior to the filing of this IDS. A copy of the Search Report is attached at Exhibit A.

This statement should not be construed as a representation that more material information does not exist or that an exhaustive search of the relevant art has been made. Nor does this statement constitute an admission by Applicants or Applicants' agent that the information provided herein is necessarily prior art to Applicants' invention. Moreover, Applicants reserve the right to establish the patentability of the claimed invention over any of the listed documents should they be applied there-against as references. Please charge any deficiency or credit any overpayment of fees to Deposit Account No. 50-0639.

Respectfully submitted,

O'MELVENY & MYERS LLP

Dated: June 11, 2003

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DKW/cp



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PATENT TRADEMARK OFFICE

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**LIST OF PATENTS AND OTHER ITEMS FOR APPLICANT'S  
INFORMATION DISCLOSURE STATEMENT**

JUN 13 2003

(Use several sheets if necessary)

**APPLICANT:**

Thomas Wagner, et al.

**FILING DATE:**

September 18, 2001

**GROUP:**

1645

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE
	AA	5,635,352	06/1997	Urdea et al.			
	AB	5,296,347	03/1994	LaMotte			
	AC	4,320,109	03/1982	Wolf et al.			

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	TRANSLATION	
							YES	NO
	AD	3715984	11/1987	Germany				
	AE	2190490	11/1987	United Kingdom				
	AF	WO 98/23956	06/1998	PCT				

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)


**EXAMINER:****DATE CONSIDERED:**

EXAMINER: Initial if reference is considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include a copy of this form with next communication to applicant